Election/Restrictions

Applicant's election with traverse of Group II in the reply filed on 3/11/2011 is acknowledged. The traversal is on the ground(s) that Waning et al does not teach all the limitations of claim 1, hence, Groups I and II share a special technical feature, i.e. the subject matter of claim 1. This is not found persuasive because Waning et al is still considered to teach all the limitations of claim 1 (see below). Briefly, the claim is not so limited as applicants suggest. The claim is broadly worded such that any "use" of a CMV enhancer/chicken β-actin promoter (CAG or CA promoter) to induce transcription or expression of the listed minus-strand RNA viruses elements anticipates the claim. Such "use" may be direct or indirect according to the instant specification (page 2, last ¶), and includes the situation taught by Waning et al because direct transcription of the RNA genome by the CAG promoter is not recited in the claim; is claimed as an alternative to claim 1 (e.g. claim 3 requires transcription of the RNA genome via a bacteriophage RNA polymerase recognition sequence, not a CAG promoter); and as exemplified in Example 5 of the instant specification (i.e. pSEV(TDK) is not taught to have a CAG promoter).

The requirement is still deemed proper and is therefore made FINAL.

Claims 2, 4, 6, 10-15, and 20-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 3/11/2011.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Japan on 1/22/2004. It is noted, however, that applicant has not filed a certified copy of the 2004-014653 application as required by 35 U.S.C. 119(b). No copy of the certified copy has been made of record in this application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Waning et al (J. Virol., 2002, cited by applicants).

Waning et al teach using a CAG promoter to express minus-strand RNA viral proteins that form a ribonucleoprotein, i.e. the NP, P and L proteins. See the ¶ linking the first and second columns on page 9285: the pCAGGS vector comprises the CAG promoter (instant specification). This is considered to also indirectly induce "transcription" of the RNA genome taught by Waning et al as these proteins are involved in replication of the RNA genome. This is similar to situations taught in the instant specification as aspects of the instant invention, i.e. page 2, last ¶ and Example 5, wherein an SeV genome is used that does not comprise a CAG promoter.

Claim 1 does not recite that a CAG promoter must directly transcribe the RNA genome, and, furthermore, only recites transcription of "a minus-strand RNA virus genome RNA." This phrase can be interpreted as transcription of any given gene in the genome, not necessarily replication of the genome itself.

Claims 16-19 and 24-26 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ito et al (Micro. Immunol., 2003, cited by applicants) as evidenced by Ito et al (J. Virol., 2001).

Ito et al teaches a plasmid (pC-T7pol) encoding the T7 RNA polymerase under control of the strong chicken β-actin promoter, see page 614, first column, first full ¶. That expression of the claimed DNA is inducible by a recombinase is an intended use limitation and does not necessarily alter the structure of the DNA as recited in claim 16 because structural alterations outside of the DNA itself can be used for such inducible expression whereas the DNA of claim 16 remains unchanged. Ito et al teach BHK cells that maintain the DNA of claim 16, and which comprise a rabies virus genome (pRC-HL(+)) which inherently has a T7 recognition sequence (Fig. 2 of Ito et al, J. Virol., 2001). See page 614, first column.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3, 5, 7-9, 16-19 and 24-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Inoue et al (J. Virol., 2003, cited by applicants) in view of Waning et al (J. Virol., 2002, cited by applicants), Ito et al (Micro. Immunol., 2003, cited by applicants), Li et al (J. Virol, 2000), and Lerch et al (2003, cited by applicants).

Inoue et al teach methods of preparing Sendai Virus (Sev) vectors lacking the envelope genes M and F by expression of these genes via plasmids driven by the CA promoter, i.e. pCALNdLw/M and pCALNdLw/F. The viral RNA genome is transcribed from pSev18+ \ΔM. See the abstract and the first and second columns, page 6420. pSev18+ \ΔM has a T7 promoter, as does pSev18+ \ΔF as taught by Li et al and Inoue et al (2001, J. Virol., cited by applicants),

absent evidence to the contrary. Inoue et al teach that remaining SeV proteins required for production of virus are provided *in trans* via expression vectors, i.e. pGEM. See page 6420, second column, first full ¶. Inoue et al do not teach expression of RNP proteins controlled by the CA promoter, or bacteriophage T7 RNA polymerase expressed via a CA promoter. Regarding claims 18 and 19, that expression of the claimed DNA is inducible by a recombinase is an intended use limitation and does not necessarily alter the structure of the DNA as recited in claim 16 because structural alterations outside of the DNA itself can be used for such inducible expression whereas the DNA of claim 16 remains unchanged.

Waning et al teach using a CAG promoter to express minus-strand RNA viral proteins that form a ribonucleoprotein, i.e. the NP, P and L proteins.

Ito et al teaches a plasmid (pC-T7pol) encoding the T7 RNA polymerase under control of the strong chicken β-actin promoter, see page 614, first column, first full ¶.

Lerch et al teaches providing a T7 RNA polymerase expression plasmid driven by the CMV promoter in order to transcribe viral genomic RNA (RSV, a minus-strand paramyxovirus) from a DNA template comprising the T7 promoter.

The claimed methods are essentially disclosed by Inoue et al with the exception of the use of a CA promoter to express the RNP proteins, and the expression of the T7 RNA polymerase from a CA promoter (Inoue et al provide this via a vaccinia virus). The ordinary skilled artisan, seeking a method to prepare SeV vectors for gene transfer, would have been motivated to use the CA promoter of Ito or Waning et al to express the SeV RNP proteins of Inoue et al because both Ito and Waning et al teach it to be a superior promoter for expression of such proteins in mammalian cells. It would have been obvious for the skilled artisan to do this

because of the known benefit of generating SeV vectors for gene transfer as taught by Inoue et al.

The ordinary skilled artisan, seeking a method to prepare SeV vectors for gene transfer, would have been motivated to use the CA promoter of Ito or Waning et al to express the T7 RNA polymerase of Ito, Inoue or Lerch et al because both Ito and Waning et al teach it to be a superior promoter for expression of such proteins in mammalian cells. It would have been obvious for the skilled artisan to do this because of the known benefit of generating SeV vectors for gene transfer as taught by Inoue et al, and the ease of using an entirely plasmid based system, as taught by Lerch et al.

Given the teachings of the cited references and the level of skill of the ordinary skilled artisan at the time of applicants' invention, it must be considered, absent evidence to the contrary, that the ordinary skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL BURKHART whose telephone number is (571)272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Burkhart/
Primary Examiner, Art Unit 1633